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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,461	03/02/2001	Esteban Cvitkovich	4512/80212	9636
27123	7590	11/23/2005		
MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			EXAMINER SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,461

Applicant(s)

CVITKOVICH ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8-30-05</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicants' Amendment/Response filed August 30, 2005 is acknowledged.

Claims 12-22 remain under consideration.

An Information Disclosure Statement filed August 30, 2005 is further acknowledged and has been reviewed.

The objection to the disclosure set forth in the last Office Action is withdrawn following the insertion of the heading "A Brief Description of the Figure" on page 16.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

There are no composition claims.

In the last Office Action claims 12-22 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of co-pending application 10/492,320.

Applicants choose to hold this issue in abeyance. Accordingly, the reject of record is maintained.

Claims 12-22 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to practice the invention. The claims are directed to the treatment of any cancer comprising administration of Et-743 at intervals of about 1-6 weeks with an infusion time of about 2 to about 24 hours. It was asserted the instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the invention without resorting to undue experimentation.

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Actions taken in applications in the past by other Examiners and positions held by them are not binding to the prosecution of the present application.

Applicants' arguments are persuasive in that there is no requirement that claims are limited to optimal regimens. The working examples in the specification provide sufficient support for the claimed subject matter. The rejection of record under 35 U.S.C. 112, first paragraph, is withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taamma et al., Eur. J. Cancer, in view of Barrera et al., Proceedings of the American Association for Cancer Research.

Taamma teaches cyclic intravenous administration of Et-743 in the treatment of various solid tumors, such as breast or ovarian cancer, for an infusion time of 24 hours every 3 weeks. The patient population included those who were designated "refractory" to standard chemotherapy, and thus these patients, as required by claim 20, had previously been treated for cancer with chemotherapy. As required by claims 21 and 22, Barrera teaches the co-administration of an additional drug with ET-743, such as doxorubicin docetaxel, cisplatin, navabine or DTIC. Variations in infusion times and dosing intervals of ET-743 are taught in the prior art. Treatment of sarcoma with ET-743 is known in the prior art as well. A period of recovery between doses to be

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administered in cycles is conventional practice. One skilled in the oncology art in view of the teachings of Taamma, and additional references of record in the present application, would have been motivated to seek an optimal dosing regimen with respect to infusion times and intervals of administration through no more than routine experimentation.

No claim is allowed.

Izbick et al., Annals of Oncology, shows in the Table on page 983 various tumor types to which ET-743 administration may be directed. A recovery time between doses of ET-743 is taught in Drugs. Fut.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).

November 20, 2005

Phyllis Spivack
Phyllis Spivack

1614 **PHYLLIS SPIVACK**
PRIMARY EXAMINER